

REMARKS/ARGUMENTS

I. Amendment to the Claims

Solely to clarify Applicants' claimed invention, original claims 1-13 have been canceled and new claims 14-23 have been added. Support for the new claims can be found in the claims and Specification as originally filed. No new matter has been added. Applicants reserve the right to pursue cancelled subject matter in a continuing application. Upon entry of this Amendment, Claims 14-23 will be pending.

II. First Double Patenting Rejection

Claims 1, 5 and 10 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting rejection as being unpatentable over claims 4-7 of co-pending application no. 11/742,687. Applicants respectfully disagree and traverse this rejection.

Claims 4-7 of co-pending application no. 11/742,687 are directed to:

(i) a compound of formula (I):

SOLID SUPPORT-LINKER-SO₂-O-(CH₂)_n-X (I) (claims 4, 5 and 8);

(ii) a radiosynthesis kit containing a compound of formula (I) (claim 6); and

(iii) a cartridge for a radiosynthesis kit containing a compound of formula (I) (claim 7). The compound of formula (I) is a solid-support precursor that is treated with ¹⁸F⁻ to form [¹⁸F]fluorohaloalkanes (see Abstract). The claims of co-pending application no. 11/742,687 are wholly unconcerned with a process for purifying a radiolabelled product as in Applicants' claimed invention. The solid-support bound scavenger group of formula (IV) of Applicants' claimed invention is used to remove excess precursor and, optionally, reaction by-product from a solution-phase radiosynthesis reaction mixture comprising the desired radiolabelled product, excess precursor and, optionally, reaction by-product, by forming a covalent bond with the excess precursor and, optionally, reaction by-product. The formation of such a covalent bond allows for separation, hence purification, of the desired radiolabelled product from the solution-phase radiosynthesis reaction mixture.

Since none of the claims of co-pending application no. 11/742,687 are directed to a process, much less a process for purifying a radiolabelled product, Applicants' claimed

invention would not be obvious in view of claims 4-7 of co-pending application no. 11/742,687. Applicants respectfully request this rejection be withdrawn.

III. Second Double Patenting Rejection

Claim 1 is provisionally rejected on the ground of nonstatutory obviousness-type double patenting rejection as being unpatentable over claims 1-3 of copending application no. 11/575,158. Applicants respectfully disagree and traverse this rejection.

Claims 1-3 of co-pending application no. 11/575,158 are directed to a method for radiolabelling insulin. The claims of co-pending application no. 11/575,158 are wholly unconcerned with a process for purifying a radiolabelled product as set forth in Applicants' claimed invention as described above in Section II.

Since Claims 1-3 of co-pending application no. 11/575,158 do not teach or suggest a process for purifying a radiolabelled product from a solution-phase radiosynthesis reaction mixture by use of a solid-support bound scavenger group, Applicants' claimed invention would not be obvious in view of co-pending application no. 11/575,158. Applicants respectfully request this rejection be withdrawn.

IV. Third Double Patenting Rejection

Claims 1 and 8 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting rejection as being unpatentable over claim 4 of copending application no. 10/539,169. Applicants respectfully disagree and traverse this rejection.

Claim 4 of co-pending application no. 10/539,169 is directed to a method for producing an ^{18}F -labelled benzothiazole tracer by treating a solid support-bound benzothiazole precursor of formula (Ib) with $^{18}\text{F}^-$. The solid support-bound precursor of claim 4 of co-pending application no. 10/539,169 is what is used to produce the desired ^{18}F -labelled benzothiazole tracer and not, as in Applicants' claimed invention as described above in Section II, to purify the already synthesized radiolabelled product from excess precursor and, optionally, reaction by-product.

Since Claim 4 of co-pending application no. 10/539,169 does not teach or suggest a process for purifying a radiolabelled product from a solution-phase radiosynthesis reaction

mixture by use of a solid-support bound scavenger group, Applicants' claimed invention would not be obvious in view of co-pending application no. 10/539,169. Applicants respectfully request this rejection be withdrawn.

V. Fourth Double Patenting Rejection

Claims 1 and 8 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting rejection as being unpatentable over claims 1-5 of U.S. Patent No. 7,223,891 (the '891 patent). Applicants respectfully disagree and traverse this rejection.

Claims 1-5 of the '891 patent are to a method for producing an ^{18}F -labelled fluorohaloalkane tracer by treating a solid support-bound haloalkane precursor of formula (I) with $^{18}\text{F}^-$. The solid support-bound precursor of the claims of '891 patent is what is used to produce the desired ^{18}F -labelled fluorohaloalkane tracer and not, as in Applicants' claimed invention as described above in Section II, to purify the already synthesized radiolabelled product from excess precursor and, optionally, reaction by-product.

Since Claims 1-5 of the '891 patent do not teach or suggest a process for purifying a radiolabelled product from a solution-phase radiosynthesis reaction mixture by use of a solid-support bound scavenger group, Applicants' claimed invention would not be obvious in view of the claims of the '891 patent. Applicants respectfully request this rejection be withdrawn.

VI. Fifth Double Patenting Rejection

Claims 1, 4 and 5 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting rejection as being unpatentable over claims 1-8, 10 and 11 of U.S. Patent No. 7,115,249 (the '249 patent). Applicants respectfully disagree and traverse this rejection.

Claims 1-8, 10 and 11 of the '249 patent are directed to the process for the production of 6-L- ^{18}F -fluorodopa (^{18}F -FDOPA) by treatment of a solid-support bound FDOPA precursor of formula (I) with a source of ^{18}F (claims 1-8); a radiopharmaceutical kit for the preparation of ^{18}F -FDOPA (claim 10); and a cartridge for a radiopharmaceutical kit for the preparation of ^{18}F -FDOPA (claim 11). The solid support-bound precursor of the claims of the '249 patent is what is used to produce the desired ^{18}F -FDOPA and not, as in Applicants' claimed invention

as described above in Section II, to purify the already synthesized radiolabelled product from excess precursor and, optionally, reaction by-product.

Since Claims 1-8, 10 and 11 of the '249 patent do not teach or suggest a process for purifying a radiolabelled product from a solution-phase radiosynthesis reaction mixture by use of a solid-support bound scavenger group, Applicants' claimed invention would not be obvious in view of the claims of the '249 patent. Applicants respectfully request this rejection be withdrawn.

VII. Sixth Double Patenting Rejection

Claims 1 and 5 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting rejection as being unpatentable over claims 1-13 of U.S. Patent No. 7,405,332 (the '332 patent). Applicants respectfully disagree and traverse this rejection.

Claims 1-13 of the '332 patent are directed to a process for the preparation of a fluorohaloalkane by treatment of a fluoro-alkyl precursor of formula (II) with a halogen XY. The precursor of formula (II) may be bound to a solid support. The solid support-bound precursor of the claims of the '332 patent is what is used to produce the desired fluorohaloalkane and not, as in Applicants' claimed invention as described above in Section II, to purify the already synthesized radiolabelled product from excess precursor and, optionally, reaction by-product.

Since Claims 1-13 of the '332 patent do not teach or suggest a process for purifying a radiolabelled product from a solution-phase radiosynthesis reaction mixture by use of a solid-support bound scavenger group, Applicants' claimed invention would not be obvious in view of the claims of the '332 patent. Applicants respectfully request this rejection be withdrawn.

VIII. First Rejection under 35 U.S.C. § 112, first paragraph

Claims 4-10 stand rejected under 35 U.S.C. §112, first paragraph as failing to comply with the written description requirement. The claim(s) contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The instant invention does not sufficiently describe the invention as it

relates to the vectors and Z-SP combinations that are compatible with the present invention, specifically, Formula IV. Applicants respectfully disagree and traverse the rejection.

New claims 17-23 correspond to the subject matter of original claims 4-10. As set forth on page 3, lns. 25-28 of the Specification, the term vector is defined and numerous examples of possible vectors are given beginning on page 2, ln. 21 through page 3, ln. 23 of the Specification. "Z" is defined on page 4, lns. 16-19 and in the claims as originally filed and is recited in the claims. "SP" is described on page 5, ln. 3 through page 6, ln. 1 of the Specification. The written description of these terms is met. Applicants respectfully request this rejection be withdrawn.

IX. Second Rejection under 35 U.S.C. § 112, first paragraph

Claims 1 and 3-12 stand rejected under 35 U.S.C. § 112, first paragraph as based on disclosure which is not enabling. The actual process steps involved in the process are critical or essential to the practice of the invention, but not included in the claim(s) is not enable by the disclosure. The steps stating how the solid support bound scavenger group of Formula IV is used are not present in the claim. Thus one cannot ascertain what process steps are being followed. The claims simply states that the process of purifying a radiolabeled product comprises using a solid support bound scavenger group of Formula IV, but does not disclose specific steps of carrying out the method. In regards to the steps disclosed in claims 3-12, it is unclear if the steps appearing in the claims 4-12 are the steps missing from the independent claim 1 or if they are additional steps necessary in the claim. This rejection has been rendered moot by the present amendment to the claims to clarify Applicants' claimed invention. Applicants respectfully request this rejection be withdrawn.

X. Third Rejection under 35 U.S.C. § 112, first paragraph

Claims 1 and 4-12 stand rejected under 35 U.S.C. § 112, first paragraph because the specification while being enabling for Z (scavenger group) selected from the group consisting of isocyanate, isothioisocyanate, thiol, hydrazine, hydrazide, aminooxy, 1,3-dipole, aldehyde, or ketone, does not reasonably provide enablement for all scavenger groups. This

rejection has been rendered moot by the present amendment to the claims. Applicants respectfully request this rejection be withdrawn.

XI. Rejections under 35 U.S.C. § 112, second paragraph

(a) Claims 1 and 3-12 stand rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, claims Claims 1 and 3-12 are rejected for being incomplete for omitting essential steps, such omission amounting to a gap between the steps. This rejection has been rendered moot by the present amendment to the claims. Applicants respectfully request this rejection be withdrawn.

(b) Claims 1 and 4-12 stand rejected under 35 U.S.C. §112, second paragraph, because it is unclear what scavenger group (Z) Applicant is claiming that is compatible with the claims. This rejection has been rendered moot by the present amendment to the claims. Applicants respectfully request this rejection be withdrawn.

(c) Claims 1 and 4-12 stand rejected under 35 U.S.C. §112, second paragraph, because it is unclear whether or not the steps listed in claim 4-12 are in addition to the ones that should be in independent claim 1 or if they are the actual steps of claim 1. This rejection has been rendered moot by the present amendment to the claims. Applicants respectfully request this rejection be withdrawn.

(d) Claims 1 and 3-12 stand rejected under 35 U.S.C. §112, second paragraph, because it is unclear which Z-SP combination(s) are compatible with the instant invention that will yield the results desired by the Applicant. This rejection has been, in part, rendered moot by the present amendment to the claims and, in part, is respectfully traversed. Based on a reading of the Specification as a whole, and given the description of “Z” on page 4, lns. 16-19 and in the claims as originally filed and of “SP” on page 5, ln. 3 through page 6, ln. 1 of the Specification, one of skill in the art would understand the metes and bounds of the claimed invention. As such, the claims are not indefinite. Applicants respectfully request this rejection be withdrawn.

Applicants respectfully request this Rejection be withdrawn.

(e) Claims 4-10 stand rejected under 35 U.S.C. §112, second paragraph, because it is unclear which vector(s) are compatible with the instant. This rejection is respectfully traversed. As set forth on page 3, lns. 25-28 of the Specification, the term vector is defined. In addition, numerous examples of possible vectors are given beginning on page 2, ln. 21 through page 3, ln. 23 of the Specification. Thus one of skill in the art would understand the metes and bounds of the claimed invention. As such, the claims are not indefinite. Applicants respectfully request this rejection be withdrawn.

XII. Rejection under 35 U.S.C. § 102(b)

Claims 1 and 3 stand rejected under 35 U.S.C. §102(b) as being anticipated by Fino (US Patent 5,290,925) (“Fino”). Applicants respectfully disagree and traverse the rejection.

Fino describes methods, kits and reactive supports for 3' labeling of oligonucleotides. (see Title). Fino describes a reactive support useful for the automated synthesis of oligonucleotides (see Abstract). The solid support of Fino is covalently bonded to a labeled trifunctional spacer complex. This covalent bond is a cleavable bond which is broken to yield the desired labeled oligonucleotide (see Abstract, Col 2, lns. 42-50). Applicants respectfully disagree that G-O-(CH₂)_n-CH(CH₂)_p-(CH₂)_m-LABEL moiety acts as a scavenger group to remove excess precursor and, optionally, reaction by-product as in Applicants' claimed invention. Fino does not teach or suggest Applicants' claimed purification process. Thus Applicants' claimed invention is not anticipated by Fino. Applicants respectfully request this rejection be withdrawn.

XIII. First Rejection under 35 U.S.C. § 103(a)

Claims 1, 4 and 5 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Luthra et al. (U.S. Patent 7,115,249)(the '249 patent). Applicants respectfully disagree and traverse the rejection.

The '249 patent describes solid-phase electrophilic fluorination. As set forth above in Section VI, the claims of the '249 patent is directed to the process for the production of 6-L-¹⁸F-fluorodopa (¹⁸F-FDOPA) by treatment of a solid-support bound FDOPA precursor of

formula (I) with a source of ^{18}F ; a radiopharmaceutical kit for the preparation of ^{18}F -FDOPA; and a cartridge for a radiopharmaceutical kit for the preparation of ^{18}F -FDOPA . The solid support-bound precursor of the claims of the '249 patent is what is used to produce the desired ^{18}F -FDOPA and not, as in Applicants' claimed invention as described above in Section II, to purify the already synthesized radiolabelled product from excess precursor and, optionally, reaction by-product.

Since the '249 patent does not teach or suggest a process for purifying a radiolabelled product from a solution-phase radiosynthesis reaction mixture by use of a solid-support bound scavenger group as recited in Applicants' claimed invention, Applicants' claimed invention would not be obvious in view of the claims of the '249 patent. Applicants respectfully request this rejection be withdrawn.

XIV. Second Rejection under 35 U.S.C. § 103(a)

Claims 1 and 5 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Brady et al. (U.S. Patent 7,405,332)(the '332 patent). Applicants respectfully disagree and traverse the rejection.

The '332 patent are directed to a process for the preparation of a fluorohaloalkane by treatment of a fluoro-alkyl precursor of formula (II) with a halogen XY. The precursor of formula (II) may be bound to a solid support. The solid support-bound precursor of the claims of the '332 patent is what is used to produce the desired fluorohaloalkane and not, as in Applicants' claimed invention as described above in Section II, to purify the already synthesized radiolabelled product from excess precursor and, optionally, reaction by-product.

Since the '332 patent do not teach or suggest a process for purifying a radiolabelled product from a solution-phase radiosynthesis reaction mixture by use of a solid-support bound scavenger group as recited in Applicants' claimed invention, Applicants' claimed invention would not be obvious in view of the claims of the '332 patent. Applicants respectfully request this rejection be withdrawn.

XV. Title

The Examiner has requested that the title of the invention be rewritten so that it is more descriptive of the instant invention. Applicants' claimed invention is a purification process. Thus the present title "Purification Methods" does describe the instant invention.

XVI. Conclusion

In view of the remarks herein, Applicants believe that each ground for rejection or objection made in the instant application has been successfully overcome or obviated, and that all the pending claims are in condition for allowance. Withdrawal of the Examiner's rejections and objections, and allowance of the current application are respectfully requested.

The Examiner is invited to telephone the undersigned in order to resolve any issues that might arise and to promote the efficient examination of the current application.

The Commissioner is hereby authorized to charge any additional fees under 37 CFR §1.16(j) or 37 CFR 1.136(a) which may be required, or credit any overpayment, to Deposit Account No. 502-665 in the name of GE Healthcare, Inc.

Respectfully submitted,

/Christine Lee/
Christine Lee
Reg. No. 42,788
Attorney for Applicants

GE Healthcare, Inc.
101 Carnegie Center
Princeton, NJ 08540
Phone (609) 514-6418
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